April Harrison: Have you ever wondered who do I turn to when I need help or advice from the NIH? Next slide. Well, today you came to the right place, as we have three key experts from the extramural team: Dr. Ashlee Lane from scientific review, Dr. Amanda Melillo from program, and Ms. Susan Medve from grants management, who are all going to walk you through their roles, responsibilities, and how they can help you navigate the grants and management system. Your first presenter today is Dr. Ashlee Lane. Next slide.

Dr. Ashlee Lane: Thank you, April, for that introduction. So if you take a look at the schematic on the left hand side of your screen, it depicts the grant life cycle. Applicants first plan their scientific submission, then they find a corresponding funding opportunity announcement. Once they do so they are then eligible to apply and submit their grant to the NIH. As a Scientific Review Officer, I am involved with the receive and refer application component as well as the review application process. At the Center for Scientific Review, otherwise known as CSR, study sections are managed by Scientific Review Officers, otherwise known as SROs. An SRO is a doctoral level professionals whose scientific background is closely aligned to the focus of the study section. The SRO manages the meeting conflicts, prepares the summary statements, and also provides information to the different institutes and centers regarding the proceedings of the review outcome. Each CSR study section has about 12 to 25 regular members who are from the scientific community, and temporary members are recruited as needed. Each study section reviews approximately 60 to 100 applications for each meeting. Now as a Scientific Review Officer, I typically get questions regarding when should I contact an SRO, what exactly is your role? So I briefly wanted to go over that. So before you submit your application or as you're preparing your application and you have questions regarding whether a particular institute or center is appropriate for your application, that's when you contact a program officer. Now if you have questions regarding what study section to submit your application to be reviewed at, that's when you contact a Scientific Review Officer. You can find contact information for program officers as well as Scientific Review Officers at the bottom of the funding opportunity announcements that you wish to apply under. Now after you submit your application, all questions then are referred to your Scientific Review Officer. You can find your assigned Scientific Review Officer's contact information located within eRA commons. Typically after you submit your application, applicants want to submit post submission materials, and you also submit those to your Scientific Review Officer. Now once the review is completed, and you have received your summary statement, at that point you then refer any questions to your assigned program officer. You will be able to see who your assigned program officer is if you look at the upper left hand corner of the first page of your summary statement. Now before I hand over the baton, I want to briefly go over ways that you can find different Scientific Review Officers' contact information. So if you go to the home page for the Center for Scientific Review, and then you click on study sections, you will see various study sections within various different areas of science. So if you sift through those different study sections and click the particular link that you're interested in, you will see the e-mail address and telephone number of the scientific review number responsible for that study section. Another way is to also use the assistant

referral tool. This tool allows you to copy and paste your aims page, and then using our artificial intelligence, CSR will recommend different study sections, and you will be able to click on those different links and get the e-mail address as well as a telephone number of the SRO for those recommended study sections. And lastly I briefly want to draw your attention to study section rosters. All rosters are available publicly at the link below, and that's another way that you can determine oh, okay, well a lot of people in my area, in my scientific area are on this roster, so maybe I should target my application to this particular study section. So that's another method. So now I want to hand over the baton to a program officer, Dr. Amanda Melillo. Amanda?

Dr. Amanda Melillo: Hi, thank you, Dr. Lane. So first as we get started I have a little poll question for you. In the fundamental session previous to this one, you've already heard a little bit about what program officers do, so now I'd like to know how many of you know who your program officer is? We could bring the poll question up. Okay, great. So about a third of people know who their program officer is, and another third maybe haven't applied year or aren't yet funded. So only a small percentage do not know who their program officer is, so that's good. That is good to know. This will help for you guys and also for people who have not yet applied. So next slide please. So for the role of a program officer going back to the grant life cycle, you may also hear the word PO for short, which just stands for program officer. We can be involved with many different phases of the grant life cycle. So for example, in the planning phase of your grant, program officers can be involved in that stage which I'll get to on the next slide. For funding opportunities, program officers actually develop funding opportunity announcements. You may also see those called FOAs, short for funding opportunity announcements. This could also be known as initiative development. So program officers are very involved in that process. And then the application goes through review, as Dr. Lane already went over. So then if the application is selected for an award this is part of what program officers also do. So we make recommendations for applications to be considered for an award by the institute director. And then finally in managing the grant award POs can provide programmatic, scientific and/or technical guidance, and that can actually occur both pre and post award. And we also can manage the oversight of a grant after it's been awarded, including monitoring the research progress, such as most grants, not all, depends on the type of grant, but have research performance progress reports, also known as RPPRs. And POs do read these reports carefully and assess the progress of the grant each year. So next slide please. So when should you contact your program officer? So before you submit your application, you can discuss the application topics if they're relevant for that particular IC. You can also discuss with your program officers the appropriate funding opportunity announcement, or what type of grant, what type of grant mechanism to apply for. For example, an R21 or an RO1. Program officers can help with those questions before you submit. They can also help provide guidance on submitting a large budget, such as a grant that's over 500K in direct costs. This is actually required that you contact your program officer before submitting a grant type like that, dependent on the funding opportunity announcement you choose. And they also can provide guidance with application preparation. So after your application goes through review and you

receive a summary statement, then you can contact your program officer to discuss the next steps, ask questions about NIH policies, and program officers can help with those steps. So a summary statement is the document you get back after an application goes to review, and so it goes through review, it's peer reviewed, and then you get a written statement back to yourself to go through and read the comments from the reviewers to understand what concerns, what they liked about the review, what concerns they might have. So during the award, so once an award is made then you can contact your program officer to discuss natural disasters or other emergencies that might affect the progress of an award. You could contact your program officer to discuss other supplement opportunities, so there's sometimes opportunities to get supplemental funds for your award. You can also contact the program about questions for prior approvals and changes to your award. And also just to discuss the progress of your funded award. And then finally after the award, you can contact your program officer to share publications or other things that may have come out of the award. And also if you plan on submitting a renewal application, so basically continuing that line of research with another application, program officers can help walk you through that process as well. So now I'm going to pass the baton over to Susan, so she can discuss the grants management perspective.

Susan Medve: Thank you, Amanda. The role of the grants management branch is to make the award and manage the award. Next slide, please. Let's first start with the roles of the chief grants management officer and the grants management specialist. The GMO is like the police officer for the grants department. It's their responsibility for completion of business management requirements and oversee making sure all award are complying with federal regulations. The GMS acts as an agent for the GMO. Next slide, please. As an agent for the GMO, we assure compliance with federal laws and NIH policies and procedures. We analyze grant applications prior to the award, and get all the required documentation necessary to prepare your award for the GMO release. We provide technical assistance, interprets NIH policies and institute procedures. We review and respond to grantee prior approval requests, and we assure that all documentation of the official grant file. Sometimes the GMS will have to work with their GMO to get a special exception, like a third of a cost extension would need an additional authority from our chief GMO. The GMO as I mentioned, they're responsible for the completion of business management requirements. They evaluate applications for administrative content and compliance with policy, interpret grants administration policies, monitors a grant administrative and fiscal aspects, assures compliance with federal laws and NIH administrative policies and procedures. The GMO is the NIH official authorized to obligate the NIH to the expenditure of funds, or to change funding amounts, budget, project period dates or other terms and conditions on the grant award. Next slide, please. When would you contact your grants manager specialist? You would contact us for all pre-award requests, our just in time process. If there's a delay in completing any paperwork required to issue your award. To discuss financial or grants administration issues, such as budget questions. Adding a foreign component. Questions about your budget or other support on your grant. Questions about any terms and conditions on your notice of award. Clarification of NIH rules and policies and also for

interpretation of grants policies. Next slide, please. So when would you want to contact your grants specialist? You'll want to contact us for any action that requires prior approval, and some of the common prior approvals are a change in scope, reducing principal investigator effort by 25 percent or more, going from a single PI to a multi PI. Carry over of unobligated funds from a previous budget period to a subsequent budget period. And only when your automatic carry over is not authorized as a term and condition on the notice of award, or if executing any carry over would cause some type of change in scope. And you want to contact us with any issues your business office does not handle or cannot advise on. Next slide, please. The next few slides provide some helpful resources. Need a reminder or quick links to understanding staff roles or contacts for the various institutes or centers, even ERA help desk? Check out NIH grants page, grants.NIH.gov/help. There are links with more policies, application guides, frequently asked questions, and a chat box that will also help direct you in the right place for resources. Next slide, please. The NIH grants home page, grants.NIH.gov, provides links to NIH policies and guidance on the entire grants process, including COVID information, electronic submission, applications, forms and instructions, how your application is reviewed, all about grants pod casts, system of award management, SAM registration, policy resubmission applications, who can apply for funding, grant writing advice and sample application and grantee policies. In addition, many of the NIH institutes and centers provide additional details to supplement this information with samples and additional information to help provide clarity. Next slide, please. Where to find the contact information for your grants manager? You can find it in the FOA. Refer to the grants contact section, or after the application was submitted you can look in eRA, and once it was awarded you can also find our information on the NOA. There's also some links here for clinical research resources, as well as the over 500K grant policy process. Next slide, please. And here are some frequently encountered acronyms. NOA is notice of award, FFR will be your federal financial report. OPERA is the office of Policy for Extramural Research Administration. CSR, as you heard, is Center for Scientific Review. RPG would be research project grant. RFA would be the request for application. A PA would be a program announcement. FOA is a funding opportunity announcement, and IC is the institute center. So visit the grants.gov website for a complete list of the NIH acronym list and glossary. Thank you, and now I'll turn it back over to April.

April Harrison: Hello, thank you for your participation today. So now we're going to get started with a few questions. The first question I have is directed toward you, Susan, and it asks do we need prior approval for re-budgeting between categories?

Susan Medve: It depends. You can re-budget within as long as it's not 25 percent or more, but there are some grants that don't allow for certain re-budgeting, whether it's a fellowship or in a training grant. Some of those categories who are not allowed to re-budget.

April Harrison: Thank you. The next question I have is .. . Okay, Amanda, I'm getting a lot of questions about what is the best way to contact your program officer?

Amanda Melillo: So if it's before you submit an application, you can always go to the NIH RePORTER website, and use their match maker tool. So that's just reporter.NIH.gov, and you'll see a match maker tool there, and that tool will allow you to put in your abstract or aims, basically the type of research you're doing, and it will come up with a list of POs that are matched at some level to the area of science. So you can find a PO that way. So if you e-mail a PO, I saw this question come up too, and no one gets back to you right away, you may want to just find another PO on that list, because all those POs may be somewhat aligned with the area of science you're looking into. And so you can always e-mail someone else, another PO, a similar question to see if maybe the research is better aligned with their institute or their program. Otherwise it's okay to always send another e-mail and ask. If you haven't heard back from them in a few days or a week, always follow up. We get a lot of e-mails.

April Harrison: Okay. The next question is for you, Ashlee. How are study sections assigned by NIH?

Ashlee Lane: That's a great question. So you have the option to suggest study sections where you want your application to go to, and you can do so using the assignment request form. And the assignment request form allows you to enter institutes and centers which may be interested in funding your application, and you can also suggest study sections. Now please note, just because you enter a study section where you want your application to be reviewed, it is not guaranteed. It's just a suggestion. April, I'm seeing another question that's very similar to review.

April Harrison: Okay.

Ashlee Lane: Can we go ahead and answer it?

April Harrison: Sure, thank you.

Ashlee Lane: So I see that someone also wanted me to give examples of post submission materials. So many FOAs allow you to submit post submission materials up to 30 days before the review meeting. An example of post submission materials include maybe you're including, you got a publication that was recently accepted, and you want to let the panel know this. Or maybe you're having a change in the contact PI, and you need to let them know that. Right now because of COVID, we're allowing applicants to submit up to one page of preliminary data. So there's a list of different acceptable materials post submission. If you Google post submission materials and NIH you will see a notice that will give you a list of all the acceptable post submission materials. And again, those are submitted directly to your SRO.

April Harrison: Thank you, Ashlee. The next question, Susan, is for you. So it's more in regards to the re-budgeting. It says that if it's less than 25 percent, there's no approval needed, so can you clarify that?

Susan Medve: Yes. As long as your re-budget is within 25 percent and it does not affect changing the scope of the work, you are allowed to re-budget. But like I mentioned before,

there are certain mechanisms that don't allow that, as far as like a fellowship or a training grant. They do have specific categories that you are not allowed to re-budget in or out of.

April Harrison: Thank you, Susan. Okay, so Amanda, another question I'm seeing frequently is what should an applicant do if they only see one PO listed and they're not getting back to them?

Amanda Melillo: So if you already have an application submitted and you see who your PO is on your summary statement, post review, and you send an e-mail, you haven't heard back, I'd first just start by sending another e-mail. Maybe not the next day, but a few days or a week later if you're not hearing back you can always follow up. If you're still not hearing back, you could always try to find a PO in that branch or maybe the branch chief for that branch, and just reach out and ask the question again. Sometimes people just miss e-mails, there may be a reason why they weren't able to get back to you, but we're always try to respond in a timely manner.

April Harrison: Okay. Also, Amanda, could you briefly describe the difference between an RFA and a program announcement, if there is any?

Amanda Melillo: Oh, yeah. So a PA is .. . It could be the parent announcement, which I mean, by parent it means it's an un-solicited application basically, NIH isn't soliciting it I a particular area of science. That's what the parent FOA is, and that's a program announcement, PA. And then an RFA is an area that the institute is soliciting for a response. So if there's some gap area that's been identified, an institute may put out an RFA to have applications come in in that particular area of science. And for RFAs, money is typically set aside to fund applications that are submitted through that RFA.

April Harrison: Thank you, Amanda. Okay, this is another question, Amanda, for you. Are POs specific for a particular IC, or can one PO span two ICs?

Amanda Melillo: So POs are assigned based on the institute, so for an example, if you submit an application and it goes to the dental institute, NIDCR, then an NIDCR program director would be assigned to that application. So anytime you're submitting an application to an NIH institute, the program officer will be assigned from that particular institute. There are a few cases where this could be a little bit different, where if you submit to, like a common fund initiative that comes out of the Office of the Director, for example, then your program officer may be at any of the institutes because they're a part of that common fund working group.

April Harrison: Okay, thank you. So this is a question for pretty much any of you. Someone wants to know if there is a green lab sustainability program for extramural. They said they saw information about intramural for NIH, but not extramural. No one's aware?

Ashlee Lane: I haven't seen anything.

Amanda Melillo: No, but thank you for bringing that to our attention.

April Harrison: Yeah, so we'll take that back and we'll find out more information about that. So thank you for bringing that question up.

Ashlee Lane: April, can I answer a review related questions?

April Harrison: Absolutely.

Ashlee Lane: So one of the questions I see, the person wants to know are summary statements available for rejected applications? So by rejected I think the person is referring to non-discussed applications. So whether your application is discussed or not discussed, your summary statement should be released within 30 days after the review.

April Harrison: Thank you.

Ashlee Lane: You're welcome.

April Harrison: Let's see, I'm trying to see something else I have went through.

Ashlee Lane: While you're going through it can I answer another review related question?

April Harrison: Sure, absolutely.

Ashlee Lane: All right. So the question is it seems like some applications are mismatched for the study section and the members. Is there any way to question or modify the study section assignment? I always suggest that applicants make sure that they are constantly checking their eRA Commons profile to see when their application is matched to a study section. And if they don't think that it's a good fit, please, please, please contact your SRO immediately and let them know that you want a different study section. It always helps to let us know what study section you want to go to, so that we can do things on the back end. You may not get the reassignment, but it's always helpful if you let your SRO know that you think there's a mismatch, and you let us know where you would like to go to instead, as soon as possible.

April Harrison: Thank you, Ashlee. Amanda, can you answer when a PI has [Indistinct] when is the best time to start applying for our grant, our mechanism?

Amanda Melillo: That's a little bit dependent on what type of K they're talking about, I'll assume it's a K99. And then that would transition to your R00. If that's the case that they're asking about. I think that applying once you have enough .. . This can be true for any case, for anytime your applying for an R01, you just want to make sure you have enough preliminary data in that application to really support your hypotheses that you're putting forward so that the reviewers can put enough thought into that. And then also just keep in mind that it takes 9 months from review to award. Actually that could be on the short end, it could even take longer. So you just always want to plan ahead. This is also a time you can reach out to your PO when you're thinking about it and they can help walk you through those timelines and the best application dates to submit.

April Harrison: Okay, thank you, Amanda. Susan, can you talk to us some about the carryover process?

Susan Medve: Well, is there anything specific about the carry over process? So what would happen in order for you to .. .

April Harrison: I think they were more in line of the time frame, so maybe you could tell them when they would typically submit a carryover and maybe talk a little bit about SNAP versus non-SNAP, and why they don't have automatic carry over and have to submit prior approval for carryover.

Susan Medve: Okay. So like I mentioned, if your grant is under SNAP, you do not need a prior approval to carry over funds. When your grant is not SNAP, the term will be on there that you need grants management approval for the carryover. Your FFR would have to be submitted and approved by OFM before the request can come to us. And what you would do is submit a package to us that has your FFR, the balance, and a spend down plan as to how you're going to use that money, and a justification as to why the money is left over, and how you're going to use it in the next segment. Once you submit all of that to us, we work with the program officer and if we approve the carryover you will get a revised NOA with the carryover money in the NOA, and there will be a term on the notice of award explaining the cost and what the carryover is for.

April Harrison: Okay, great. Thank you. So another question that's related .. . I'm sorry?

Amanda Melillo: I was just going to ask Susan to explain what SNAP is.

Susan Medve: Snap is the streamline and they do not, like I said, you don't have the carry over. SNAP does have carry over authority.

April Harrison: Okay, so the next question is can you elaborate, Susan, on the change of scope, and when they should notify their GMS if there's a change in scope?

Susan Medve: A change in scope regarding the carryover or just a change in scope?

April Harrison: No, it's just a change in scope in general from the question.

Susan Medve: Yes, if there is any change in scope, you would contact us and then we would actually go back program, because that's a more scientific area as far as making sure that that is within the scope, and once they approve what you're requesting to do then the official approval will come from the grants department.

April Harrison: Okay, so this is another question I think, Amanda, you probably would be able to answer. In addition to FOAs, are there are any funding that is open for applications on an ongoing basis without an announcement?

Amanda Melillo: Could you repeat the end of that question?

April Harrison: Oh, sure. I said that other than the ongoing announcements, are there other .. . It says in addition to FOAs, are there any funding that's open for applications on an ongoing basis without being an announcement.

Amanda Melillo: So any type of funding that the NIH will be putting out has some type of announcement. There are some types of funding mechanisms that the NIH uses that don't come through FOAs or funding opportunity announcements, such as some come through the

other transaction authorities is a newer mechanism that's been used by NIH, which comes through a research .. . It's similar to an FOA, it's just slightly different, but there always be some type of announcement out there that will have a call for applications. So I don't know if that's exactly answering the question. I also just want to clarify, I wasn't thinking when I answered the last question. I think I said that there was 9 months between review to award, I meant to say 9 months between application. So when you submit the application to a potential award, that's the 9 month period, but it could even be longer than that.

April Harrison: Did any of you see any other things that you may have wanted to answer? I'm trying to go through and go to ones that I don't think we've touched on.

Amanda Melillo: I can answer one more here.

April Harrison: Okay, sure. Go ahead, Amanda.

Amanda Melillo: It says if a PO does not participate and study section does not have a say in proposals, the SRO and the panel review suggests for funding, then what's the benefit of discussing with the PO before submission? Is there a guarantee that the PO will even be assigned to your application? So you want to discuss prior to submission with your PO to make sure that the application is an appropriate fit for the institute, not the study section, so I think that's just a little clarity there. Especially if it's in response to a particular funding opportunity announcement that comes out from one institute, you want to make sure that whatever idea that you have that you're going to put in fits, because if you submit an application to a particular funding opportunity announcement that's not a general one and the appropriate IC is not signed on, then your application could get withdrawn without review. So you always want to just check in on that prior to application.

April Harrison: Okay. The next question says if the PO does not participate in a study section, does not have a say in a proposal .. .

Ashlee Lane: We just answered that one.

Amanda Melillo: That's the one I just did.

April Harrison: Oh, I'm sorry. Okay. Okay, so the next question is .. . Susan they said you got cut off when you were talking about SNAP, so can you talk about SNAP again?

Susan Medve: SNAP is the streamlined process. They do have automatic carryover.

Amanda Melillo: I'll just say SNAP stands for streamlined non-competing award process.

Susan Medve: Sorry, thank you, Amanda. Sorry. Thank you.

Amanda Melillo: It's just applied to certain types of award, like Susan had said.

April Harrison: All right, so normally larger awards, I am a specialist to, but I'm trying to manage the questions. I would just like to plug in that normally the larger awards are the ones that are non-SNAP. So those are you P50, your [Indistinct] of agreement. So use or other larger research

mechanisms, such as R35. Also fellowships are not SNAP awards, but typically R1s are SNAP awards, and Ks, stuff like that. So, okay we'll keep asking the questions.

Amanda Melillo: I can answer another.

April Harrison: Okay, go ahead.

Amanda Melillo: So this is who do I contact for the next step for an application that has gone through counsel review since August, but has been pending administrative review and my eRA Commons. So you would contact your PO for that. If you still don't hear back, like I said previously, just try to reach out again.

April Harrison: Okay, so the next question says are study sections for training awarded differently from other study sections, Ashlee?

Ashlee Lane: So, by different, they're different because they're reviewing fellowship applications versus RO1 applications. The panels are constructed in the same manner, so of course you have experts in your field. Like I mentioned before, RO1s and R21s are reviewed separately than fellowships. So F31s, F32s, KO1s, and K99s, those are reviewed together in a fellowship panel. Usually all F awards are discussed. So F awards usually aren't triaged.

April Harrison: Okay, well can't either Ashlee or you, Amanda, talk about, one of the applicants was saying that they submitted an application for one IC, but it ended up in another IC, and now their program officer is completely different. They're asking what should they do?

Ashlee Lane: I would recommend that one, they contact the PO that they were in contact with, and also reach out to the Division of Receipt and Referral at NIH, because they assign the institutes and centers when applications are initially submitted to NIH. And they should be able to help them. That is the Division of Receipt and Referral at NIH.

April Harrison: Okay. Okay, so now we actually have less than 5 minutes left in the presentation, so if any of you want to answer a last question you can go ahead and do so before I end out this session. Okay.

Amanda Melillo: Sure. One question here asked if there's a difference between a PD and a PO. A PD is a program director, PO, program officer. No. Some institutes just call them program directors and some say program officers, but same.

Ashlee Lane: I see one of the questions they say why does an application not get discussed? So as I mentioned before, study sections usually get between 60 and 100 applications, and typically we discuss the top 50 percent of applications. So if the preliminary score isn't within the top half, then we do not discuss the bottom half. But you will still get a summary statement. So regardless of whether or not your application was discussed or not, you will get a summary statement to let you know the evaluation from your assigned reviewers.

April Harrison: Okay, thank you presenters and participants for this informative session. If you have any additional questions, please visit our exhibit hall booth for chats and one-on-one

opportunities. You can always find contact information in the help section at grants.NIH.gov site. Your feedback is very important to us. Please take a moment to let us know what you thought by clicking the session feedback button located within the description and presenters on the auditorious list of the session. When you are completely done with the seminar, please also complete the overall survey form in the navigation bar at the top of the page. Thanks again, and have a great day.

Ashlee Lane: Thank you.

April Harrison: Thank you, everyone.